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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,184	04/11/2005	Arieh Sher	798/18	6320
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			EXAMINER	
			LAMPRECHT, JOEL	
			ART UNIT	PAPER NUMBER
			3737	
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			06/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/531,184

Applicant(s)

SHER, ARIEH

Examiner

Joel M. Lamprecht

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/27/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13, 16-25, 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by McKenzie et al (US 5,993,469). McKenzie et al disclose a method and apparatus for reducing restriction of blood flow in a lumen of a blood vessel comprising inserting imaging guidewire into the lumen capable of generating cross-sectional images of the lumen (Col 9 Line 35-50, Col 11 Line 65-Col 12 Line 65, Col 18 Line 30-45), propelling a catheter including a "working head" over the imaging system to the plaque (Col 11 Line 16-65), scanning the lumen with the imaging system to image the lumen (Col 11 Line 65-Col 12 Line 65), positioning the catheter in the lumen using a position element and monitoring the image to determine if the head is positioned in a desired location (Col 18 Line 5-45), and finally operating the working head to remove the intraluminal plaque (Col 19 Line 10-Col 20 Line 5). The working head disclosed by McKenzie et al contains a cutting edge which is operative when rotated and is capable of operation prior to traverse of the plaque (Col 16 Line 35-60), positioning elements include a number of balloons which can circumferentially surround the catheter (Col 18 Line 5-45), contains a control system which can aid in positioning, scanning, inserting, monitoring (Col 12 Line 35-Col 13 Line 17, Col 19 Line 10-30), and operating the device

and can be operated by inputs from the operator, a removal device including for removal of the plaque (Col 17 Line 50-Col 18 Line 3), a therapeutic lumen and a central vacuum lumen for removal of the plaque removed by the cutting device (Col 12 Line 10-35).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13, 16-25, 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKenzie et al in view of Milo et al. McKenzie et al disclose all that is listed above, mainly a method and apparatus for reducing restriction of blood flow in a lumen of a blood vessel comprising inserting imaging guidewire into the lumen capable of generating cross-sectional images of the lumen (Col 9 Line 35-50, Col 11 Line 65-Col 12 Line 65, Col 18 Line 30-45), propelling a catheter including a "working head" over the imaging system to the plaque (Col 11 Line 16-65), scanning the lumen with the imaging system to image the lumen (Col 11 Line 65-Col 12 Line 65), positioning the catheter in the lumen using a position element and monitoring the image to determine of the head is positioned in a desired location (Col 18 Line 5-45), and finally operating the working head to remove the intraluminal plaque (Col 19 Line 10-Col 20 Line 5). The working head disclosed by McKenzie et al contains a cutting edge which is operative when rotated and is capable of operation prior to traverse of the plaque (Col 16 Line 35-60),

positioning elements include a number of balloons which can circumferentially surround the catheter (Col 18 Line 5-45), contains a control system which can aid in positioning, scanning, inserting, monitoring (Col 12 Line 35-Col 13 Line 17, Col 19 Line 10-30), and operating the device and can be operated by inputs from the operator, a removal device including for removal of the plaque (Col 17 Line 50-Col 18 Line 3), a therapeutic lumen and a central vacuum lumen for removal of the plaque removed by the cutting device (Col 12 Line 10-35).

McKenzie et al do not disclose the use of an Archimedes screw for removal of the plaque, rather they teach a claw and suction system, nor do they teach the use of a mirror which allows for angular imaging within the lumen, instead they teach the use of a flexible catheter head capable of turning to view the arterial walls.

Attention is then directed to the secondary reference by Milo et al which teaches in the same area of endeavor the use of an Archimedes screw device for plaque removal (Fig 5, 8 and Col 15 Line 50 – Col 16 Line 58) as well as the use of a mirror affixed upon a system for the purpose of minimal trauma to the arterial walls during imaging (Col 13 Line 50-Col 14 Line 50). The mirror assembly is not foldable as listed within the present application but is contained within the housing to provide the same functionality, mainly the reduction of stress and trauma on the vessel wall. Milo et al additionally disclose control systems in more detail than those from McKenzie and also include similar rotational cutting and imaging systems incorporated within their device. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the plaque-removal system of McKenzie et al with the screw removal

system and mirror-imaging system of Milo et al for the purpose of providing an alternate means of removal and a less-traumatic method of imaging the arterial walls.

3. Claims 1, 14, 15, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKenzie et al in view of Masch (US 4,728,319). McKenzie et al disclose all that is listed above but fail to include specifics on the rotational speeds of the cutting head. As the listed RPMs within the current applications are outside of the norms for traditional cutting with a high speed head attention will be directed to the secondary reference by Masch that describes the use of a cutting element with a screw-like design which is used at 10-60 RPM for the removal of plaque elements within the body (Fig 1-5, Col 6 Line 20-55). It would have been obvious to one of normal skill in the art at the time of the invention to have enhanced the teachings of McKenzie et al with those of Masch et al to provide a low-speed cutting element for removal of plaque within arteries of the body.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joel M. Lamprecht whose telephone number is (571) 272-3250. The examiner can normally be reached on Monday-Friday 7:30AM-4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JML
6/7/07



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